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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,310	11/23/2001	Kunio Doi	215808US20	2678
22850	7590	07/14/2004		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER DASTOURI, MEHRDAD	
			ART UNIT 2623	PAPER NUMBER

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/990,310

Applicant(s)

DOI ET AL.

Examiner

Mehrdad Dastouri

Art Unit

2623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-9, 12/7, 12/8, 12/9, 13/7, 13/8 and 13/9 is/are allowed.
- 6) ☒ Claim(s) 1-6, 10, 11, 12/1-12/6, 12/10, 12/11, 13/1-13/6, 13/10, 13/11 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed January 28, 2004, has been entered and made of record.
2. The Declaration under filed on January 28, 2004 under 37 C.F.R. § 1.131 has been considered and it will overcome the U.S. Patent Publication 2002/0172403 reference.

3. Objection to Claim 12 has been withdrawn in view of Applicants' amendment.

Applicant's arguments filed January 28, 2004, regarding alternate rejection of Claims 1-14 have been fully considered but they are not persuasive.

Applicants argue that prior arts of record (Doi '374 and Ema) do not disclose patient' age or gender as a factor in evaluating whether a pulmonary nodule is malignant.

The examiner disagrees and indicates that sex (gender) and age (date of birth) of the patient are among the factors considered by Ema (Tables 5, 6, 7 and 10).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5, 12/1-12/5, 13/1-13-5 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over XU (WO 99/42950) in view of SATA (JP 05-130986).

As per Claim 1, XU teaches:

obtaining at least one computed tomography medical image of the pulmonary nodule (Figures 1(a)-1(c); Pages 5-6);

extracting image features of the pulmonary nodule from the at least one computed tomography medical image (Pages 5-6);

evaluating whether the pulmonary nodule is malignant based on an examination of a total of seven of the patient or image features (Page 7).

XU states that lung cancer is leading cause of cancer death in men and women (Page 2), but does not specifically teach using patient feature data (sex and age) of the person having pulmonary nodules.

SATA teaches:

obtaining at least one patient feature (See Constitution).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the comparison processing feature of SATA which include the pertinent patient data that may cause differences in the comparison of nodule data in the system of XU to further reduce the chances of false positive results (e.g., comparing cancerous reference nodules of a 61-year old male patient with a 40 year history of continuous cigarette smoking versus a 25-year old female patient with no cigarette smoking history).

As per Claim 2, XU teaches:

wherein the step of obtaining at least one computed tomography medical image comprises obtaining a medical X-ray image (Page 2).

As per Claim 3, SATA teaches:

wherein the step of obtaining at least one computed tomography medical image comprises obtaining at least one low-dose computed tomography image (See Constitution, X-ray CT Device).

As per Claim 4, SATA teaches:

wherein the step of obtaining at least one patient feature comprises obtaining at least one of sex and age of the patient having the pulmonary nodule (See Constitution).

As per Claim 5, combined teachings of XU and SATA (Processing X-ray CT digital images of SATA according to XU procedures) disclose:

identifying image features based on an outline of the at least one computed tomography medical image of the pulmonary nodule (XU, Page 5, 122 pulmonary nodules in chest radiographs verified by CT scans);

identifying image feature based on linear patterns of the at least one computed tomography medical image of the pulmonary nodule (XU, Page 6, Edge Detection);

identifying image feature based on edge orientation of an edge gradient of the at least one computed tomography medical image of the pulmonary nodule (XU, Page 6, second Paragraph);

identifying image feature based on gray-level distribution of the at least one computed tomography medical image of the pulmonary nodule (XU, Page 6-7, Histogram);

identifying image feature based on gray-level distribution of an edge gradient of the at least one computed tomography medical image of the pulmonary nodule (XU, Pages 6-7);

identifying image feature based on the relationship between two histograms in the inside and outside regions of the segmented nodule of the at least one computed tomography medical image of the pulmonary nodule (XU, Page 7; Figure 7);

identifying image feature based on the relationship between two histograms in the inside and outside regions of the segmented nodule of an edge gradient of the at least one computed tomography medical image of the pulmonary nodule (XU, Pages 7-9; Figures 6-10).

As per Claims 12/1-12/5 and 13/1-13-5, they depend upon any of the rejected Claims 1-5 above and analogous remarks apply.

As per Claim 14, it merely recites a broader version of Claim 1 and analogous remarks apply.

6. Claims 6, 10, 11, 12/6, 12/10, 12/11, 13/6, 13/10 and 13/11 are rejected under 35 U.S.C. 103(a) as being unpatentable over XU (WO 99/42950) further in view of SATA (JP 05-130986) and Doi (U.S. 5,289,374).

Neither XU nor SATA explicitly disclose identifying at least one of the specific image features recited in Claim 6.

Doi teaches:

identifying the degree of circularity of the outline (Column 4, Line 47);

identifying the degree of irregularity of the outline (Column 4, Line 47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify XU and SATA combination in accordance to the teachings of Doi to incorporate further limitations recited in Claim 6 because it will increase the accuracy and the reliability of diagnostic system.

As per Claim 10, Doi teaches:

wherein the step of extracting image features consists of extracting the effective diameter of the pulmonary nodule and the contrast of the pulmonary nodule (Column 2, Lines 40-51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify XU and SATA combination in accordance to the teachings of Doi to incorporate further limitations recited in Claim 10 because it will increase the accuracy and the reliability of diagnostic system.

As per Claim 11, it would have been obvious to one of ordinary skill in the art to evaluate if the pulmonary nodules are malignant is based on the examination of a plurality of medical images (e.g., three medical images) because it will increase the accuracy and reliability of diagnostic procedures.

As per Claims 12/6, 12/10, 12/11, 13/6, 13/10 and 13/11, they depend upon any of the rejected Claims 6, 10 and 11 above and analogous remarks apply.

Allowable Subject Matter

Claims 7-9, 12/7, 12/8, 12/9, 13/7, 13/8 and 13/9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In particular, Claims 12/7, 12/8, 12/9, 13/7, 13/8 and 13/9 should be rewritten to explicitly recite limitations of the base claim and any intervening claims.

Claim 7 of the instant invention recites:

identifying the magnitude of line patterns for inside region of a segmented nodule of the medical image; and

identifying the magnitude of line patterns for outside region of a segmented nodule of the medical image.

Claim 8 of the instant invention recites:

identifying radial gradient index computed by the mean absolute value of a radial gradient projected along a radial direction for the inside of a segmented nodule of the medical image;

identifying radial gradient index computed by the mean absolute value of a radial gradient projected along a radial direction for the outside of a segmented nodule of the medical image;

identifying tangential gradient index computed by the mean absolute value of a radial gradient projected along a radial direction for the inside of a segmented nodule of the medical image;

identifying tangential gradient index computed by the mean absolute value of a radial gradient projected along a radial direction for the outside of a segmented nodule of the medical image.

Claim 9 of the instant invention recites:

the step of obtaining the patient features consist of obtaining the sex of the patient; and

the step of extracting image features consists of extracting image features consists of extracting effective diameter of the pulmonary nodule, contrast of the pulmonary nodule, overlap measure of two gray-level histograms for the inside and outside regions of a segmented nodule of the medical image, overlap measure of two

gray-level histograms of the inside and outside region of a segmented nodule of an edge gradient of the medical image.

Claims 12/7, 12/8, 12/9, 13/7, 13/8 and 13/9 recite computer readable medium and system corresponding to method Claims 7-9, respectively, and are therefore allowable.

The features identified are neither discussed nor suggested by the prior arts of record.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mehrdad Dastouri whose telephone number is (703)

305-2438. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amelia Au can be reached on (703) 308-6604. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MEHRDAD DASTOURI
PRIMARY EXAMINER

Mehrdad Dastouri

Mehrdad Dastouri
Primary Examiner
Art Unit 2623
July 10, 2004